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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,312	02/15/2002	John McKenzie	271/094	3792

30452 7590 01/25/2005

EDWARDS LIFESCIENCES CORPORATION  
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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/077,312

Applicant(s)

MCKENZIE ET AL.

Examiner

Urmi Chattopadhyay

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-12 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-10 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Request for Continued Examination***

1. The request filed on 12/17/04 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 10/077,312 is acceptable and a RCE has been established. An action on the RCE follows.
2. Claims 1-3 and 6-12 are currently pending, of which claim 11 is withdrawn. The claims being considered for further examination on the merits are 1-3, 6-10 and 12.

### ***Interference***

3. The examiner acknowledges that a formal request for declaration of interference will be provided upon indication that all pending rejections have been removed, and that at the present time, such a request is not ripe because the present application remains under rejection.

### ***Response to Amendment***

4. The Declaration under 37 CFR 1.132 filed 12/17/04 is sufficient to overcome the rejection of claims 1-3, 6-10 and 12 under 35 U.S.C. 102(b) based upon showing of the filter mesh material of the current application and of priority application 08/854,806 (USPN 6,231,544) inherently having varying porosity. Claims 1-3, 6-10 and 12 receive benefit of priority application 08/854,806, and have an effective filing date of May 12, 1997. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bajaj (USPN 5,053,008) and Kletschka (USPN 4,794,928).

***Response to Arguments***

5. Applicant's arguments, see pages 6-8, filed 12/17/04, with respect to the objection to the specification have been fully considered and are persuasive. Incorporation of priority application 08/854,806 by reference satisfies specification completeness and antecedent basis for claimed subject matter requirements. The objection of the specification has been withdrawn.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3, 6-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bajaj (USPN 5,053,008, as cited in applicant's IDS) and Kletschka (USPN 4,794,928).

Bajaj discloses a catheter apparatus for use in a body passage with all the elements of claim 1, but is silent to the upstream member being a sealing member for creating a seal between the upstream end of the expandable conduit and an internal wall of the body passage. See Figure 2 for a catheter apparatus (12) comprising an expandable conduit (18) defined by a filter mesh (22) (column 7, lines 55-63) mounted on a catheter shaft (16) (column 6, lines 2-4). As admitted by applicant, the filter mesh will inherently have varying porosity. See Figures 1 and 2 for the expandable conduit (18) having an upstream end and a downstream end. The expandable conduit (18) has a collapsed position in which the expandable conduit is collapsed toward the catheter shaft and an expanded position in which the upstream end of the expandable conduit is

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open to fluid flow (column 6, lines 6-11 and column 7, lines 29-36). An upstream member (20) at the upstream end of the expandable conduit (18) encircles and hugs an internal wall of the body passage without causing trauma thereto (column 8, lines 21-22). Kletschka teaches a trap/barrier membrane (23) forming a seal with the interior lining (2) of the vessel (1) to be treated in order to prevent substantially all physiologically significant particles from escaping from an obstruction site and remove substantially all potential embolic material. See Figure 12, column 1, lines 6-9, column 2, lines 36-40 and column 8, lines 52-56. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Kletschka to modify the upstream member of Bajaj by making it a sealing member for creating a seal between the upstream end of the expandable conduit and internal wall of the body passage without causing any trauma thereto in order to prevent substantially all physiologically significant particles from escaping an obstruction site and remove substantially all potential embolic material.

Claim 2, see column 6, lines 5-6 for the upstream member being an inflatable toroidal balloon (20).

Claim 3, see Figures 1 and 2 for a perfusion lumen within the catheter shaft (16) in fluid communication with a space exterior to the expandable conduit (18).

With respect to claim 6, Bajaj is also silent to the catheter apparatus further comprising an occlusion member for selectively occluding the expandable conduit. Kletschka teaches an angioplasty device for treating acquired obstruction of the pulmonary artery, wherein an inflatable balloon (4) compresses the obstruction and a trap/barrier membrane (23) prevents substantially all potential embolic material from escaping the obstruction site, thus preventing

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the occurrence of unfavorable side effects from angioplasty treatment and procedures. See Figure 12, column 1, lines 6-20 and column 2, lines 36-40. When the balloon is inflated at the obstruction site, it is providing as an occlusion member by selectively occluding the trap/barrier membrane. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Kletschka to modify the catheter apparatus of Bajaj by including an inflatable occlusion balloon (claims 6 and 10) that selectively occludes the expandable conduit in order to compress and crush an obstruction in the pulmonary artery for removal thereof in addition to preventing pulmonary emboli.

Claim 7, see Figure 2 and column 9, lines 35-39 for an infusion lumen (64) within the catheter shaft (16) having an infusion port that would be upstream of the occlusion member.

Claim 8, see Figures 1 and 2 for a perfusion lumen within the catheter shaft (16).

With respect to claim 9, Bajaj is also silent to the catheter apparatus further comprising a tubular sheath sized to fit over the expandable conduit when in the collapsed position. Kletschka teaches a sheath sized to fit over the trap/barrier membrane (23) in order to hold down expansion springs (18) in the collapsed position until expansion is desired. See Figure 14 and columns 8-9, lines 63-10. The expandable conduit (18) of Bajaj includes metallic struts (28) that are biased outwardly to make the expandable conduit (18) biased in the open position. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Kletschka to modify the catheter apparatus of Bajaj by including a tubular sheath sized to fit over the expandable conduit (18) in order to hold down the outwardly biased metallic struts (28) in the collapsed position until expansion is desired.

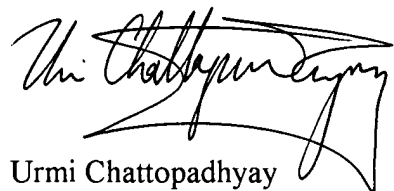
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Claim 12, see Figure 2 for the catheter shaft (16) being positioned internal to the expandable conduit (18).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

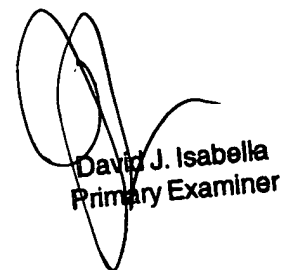
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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